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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,353	07/30/2001	Svetlana Alexandrovna Morenkova	P67002US0	1986

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JACOBSON HOLMAN PLLC  
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WASHINGTON, DC 20004

EXAMINER
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WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/890,353**

Applicant(s)  
**Morenkova**

Examiner  
**Randall Winston**

Art Unit  
**1654**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above, claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some\* c) ☐ None of:

- ☒ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

Applicants' election with traverse of Group I, Claims 19-25 in Paper No. 7 is acknowledged. The traversal is on the grounds that the applicant argues that the present claims do relate to a general inventive concept under PCT Rule 13.1 and PCT 13.2 since the inventions of both groups contain the same special technical feature. Therefore, applicants respectfully submit that the restriction requirement may be withdrawn.

Applicants' argument is not found persuasive because, as the Examiner explained in the Restriction Requirement (Paper No. 5), the special technical feature of Group I's composition which is drawn to an insulin-containing medicine for peroral use containing insulin and an auxiliary substance is mutually exclusive from Group II's method which is drawn to a method for derivation of insulin-containing medicine for peroral use, including the erythrocytes from fresh mammal blood etc. Thus, the special technical feature of Group II is missing from Group I, and vice-versa and therefore, there is no Unity of Invention between Group I's composition and Group II's method (i.e., Group II's method comprises of steps (i.e., of different temperatures and/or time and/or amounts and/or active ingredients) different from of what Group I's composition requires).

The restriction requirement is still deemed proper and is therefore made final.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the terms "stitching agent." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning "stitching agent." There is no definition of "stitching agent" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 19-25 are rejected under 103(a) as being unpatentable over Morenkova (see Derwent abstract, ACC-NO: 1997-041104) in view of Cho et al. (US 5665700).

Applicant claims an insulin-containing medicine for peroral use comprising a stitching agent (i.e. glutarite dialdehyde (?)), insulin (i.e. of a form), erythrocytes which are excreted from fresh pig, livestock or horse blood or from fresh human blood, and an auxiliary substance (i.e. gelatin) whereas the above active ingredients are of various amounts/ranges.

Morenkova teaches the claimed invention' insulin-containing medicine for peroral use comprising a stitching agent (i.e. glutarite dialdehyde), insulin, erythrocytes which are excreted from animal or humans (see, abstract). Morenkova does not teach gelatin contained within an insulin-containing medicine.

Cho et al. beneficially teach gelatin contained within an insulin preparation for packing purposes (see, e.g. column 13 line 2 and column 17 lines 19-22).

It would have been obvious to one of ordinary skilled in the art at the time the claimed invention was made to modify Morenkova to include gelatin as beneficially disclosed by Cho et al. for packing purposes of an insulin-containing medicine. Thus, the adjustment of these and other conventional working conditions (e.g. the insulin form and/or active ingredients amounts/ranges), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Please note the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made a different process. (see, e.g. MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER